K010550

APR 2 4 2001

bioMérieux

510(k) SUMMARY

VIDAS Total Prostate Antigen (TPSA) Assay

A. Submitter Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nancy Weaver
Phone Number:	314-731-8695
Fax Number:	314-731-8689
Date of Preparation:	February 21, 2001

B. Device Name:

Trade Name:	VIDAS Total Prostate Antigen (TPSA) Assay
Common Name:	Enzyme-linked Fluorescent Immunoassay (ELFA) for the quantitative detection of prostate specific antigen.
Classification Name:	21 CFR 866.6010, Tumor-associated antigen immunological test system

C. Predicate Device Name:

Trade Name:	TOSOH MEDICS Corporation AIA PACK® Total PSA assay

D. Device Description:

The VIDAS Total Prostate-Specific Antigen (TPSA) Assay is an enzyme-linked fluorescent immunoassay (ELFA) performed in an automated VIDAS® instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as the solid phase as well as a pipettor for the assay. Reagents for the assay are in the sealed TPSA Reagent Strips.

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After preliminary wash and sample dilution steps, the sample is cycled in and out of the SPR for a specified length of time. Prostate specific antigen

present in the specimen will bind to the monoclonal anti-PSA immunoglobulin coating the interior of the SPR. Unbound sample components are washed away. Alkaline phosphatase labeled antibody is then incubated in the SPR where it binds with any prostate specific antigen bound to the SPR wall. A final wash step removes unbound conjugate.

A fluorescent substrate, 4-methylumbelliferyl phosphate, is introduced into the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The optical scanner in the instrument measures the intensity of fluorescence. When the VIDAS TPSA assay is completed, the results are analyzed automatically by the computer, a test value is generated, and a report is printed for each sample.

E. Intended Use:

VIDAS TPSA is intended for use with a VIDAS (VITEK ImmunoDiagnostic Assay System) instrument as an automated enzyme-linked fluorescent immunoassay (ELFA) for the quantitative measurement of total prostate specific antigen in serum. The VIDAS TPSA assay is indicated as an aid in the management of patients with prostate cancer.

F. Technological Characteristics Summary:

Major Similarities Include:

1. Both test are quantitative enzyme immunoassays that detect the presence of prostate specific antigen in human serum.
2. Both assays use 4-methylumbelliferyl phosphate as a substrate.
3. Both tests are run on automated immunoassay systems.

Major Differences Include:

1. The VIDAS Assay uses sealed Reagent Strips. All reagents necessary to perform the VIDAS assay are contained in the reagent strip. No additional preparation is required.

   The TOSOH assay uses test cups that have a dry-reagent format. Other liquid reagents required for the assay are prepared in bulk and dispensed by the TOSOH instrument.

2. The VIDAS assay uses a SPR for antigen capture.
   The TOSOH assay uses magnetic beads to capture antigen.

G. Performance Data:

Nonclinical Testing:

	TOSOH AIA-PACK PA	VIDAS TPSA
Specificity	PAP = 0.0%	PAP = 0.0028%
Sensitivity:	Estimated to be 0.1 ng/ml	0.07 ng/ml
Expected Value for healthy males	0.47 - 3.04 ng/ml (n = 187)	< 1.0 - 8 ng/ml 1 (n=400)
Interference	No interference from hemoglobin, bilirubin, lipids, protein	No interference from hemoglobin, bilirubin, lipids, protein
Intra-run precision CV	2.9% - 3.9%	2.3% - 8.6%
Inter-run precision CV	2.1% - 3.9%	0.0% - 2.4%
Dilution % Recovery	95.5% - 109.0%	84.9% - 100.0%

Clinical Testing:

Three groups of clinical samples were evaluated to determine the equivalence of the VIDAS TPSA assay to the TOSOH AIA-PACK PA Assay. Samples from 400 healthy patients were tested with both assays. A regression analysis this data gave an R^2 of 0.98 indicating a high degree of agreement between the predicate and test devices. A cohort of patients prostate disease were also evaluated. Regression analysis of samples from men with benign prostate disease (n=200) and those with prostate cancer (n= 100) both gave R^2 values of 0.99. Finally a set of 60 serial samples from cases of prostate cancer were evaluated with both assays. The VIDAS assay correctly tracked the TOSOH assay 99.7% of the time in the monitored patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 4 2001

Ms. Nancy Weaver
Staff Regulatory/Clinical Affairs Specialist
BioMerieux, Inc.
595 Anglum Road
Hazelwood, Missouri 63042-2320

Re: K010550
Trade Name: VIDAS® Total Prostate Specific Antigen (TPSA) Assay
Regulation Number: 21 CFR§ 866.6010
Regulatory Class: II
Product Code: LTJ
Dated: February 21, 2001
Received: February 26, 2001

Dear Ms. Weaver:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K010550

Device Name: VIDAS Total Prostate Specific Antigen (TPSA) Assay

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number

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Concurrence of CDRH, Office of Device Evaluation (ODE)